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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,442	02/12/2002	Joachim Bug	KUTZ 3	3636
23599	7590	01/08/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
10/049,442	BUG ET AL.	
Examiner	Art Unit	
Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 October 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) 11 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-10,12 and 13 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____.

The application should be reviewed for errors and conformity with domestic practice. Error occurs, for example, in the spelling of “mulilayer tatalet” and “at tablet” in claim 13 and of “am” in claim 11, last line.

In keeping with scientific custom, the names of genera and species of microorganisms should be underlined or italicized throughout the specification and claims.

The election without traverse filed 10/27/03 is acknowledged. Claims 1-10 and 12-13 are being considered on the merits.

Claim 11 is withdrawn from consideration as directed to a non-elected invention.

The information disclosure statement filed 7/12/02 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. The list of “non-patent literature” improperly includes a listing of Japanese patent abstracts. Correction is required, including dates of the patents.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is confusing in the recitation of “bifidus bacteris”. It is unclear what is intended. Is it the genus “*Bifidobacterium*”

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of

the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, at least claims 3, 4, 8, 10 and 13 recite a broad recitation, and the claim also recites “preferably” and/or “more preferably” followed by the narrower statement of the range/limitation.

Claim 9 is vague and indefinite in the recitation of “further nutritionally relevant additives”, since the nutritional target is uncertain.

Claim 6 is vague and indefinite in the use of multiple “and/or”, since it is uncertain what is intended, particularly in combination with “essentially consisting of”.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Guttag.

The claims are directed to an enterically coated “oral administration form” or tablet containing probiotic microorganisms having one or more layers.

Guttag discloses an enterically coated “oral administration form” or tablet containing probiotic microorganisms. See, e.g., Example 1.

Claims 1-4, 9, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Toyoichi *et al.* or Kominato *et al.* or Sigurta.

The claims are directed to an enterically coated “oral administration form” or tablet containing probiotic microorganisms having one or more layers.

Toyoichi *et al.*, Kominato *et al.* and Sigurta each discloses an enterically coated “oral administration form” or tablet containing probiotic microorganisms. See, e.g., Toyoichi *et al.*, Kominato *et al.*, Abstracts, and Sigurta, Examples.

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guttag taken with Kim *et al.* and Sigurta.

The claims are directed to an enterically coated "oral administration form" or tablet containing probiotic microorganisms having one or more layers including shellac as an enteric coating and another layer is polyvinylpyrrolidone.

Guttag discloses an enterically coated "oral administration form" or tablet containing probiotic microorganisms. See, e.g., Example 1.

The reference differs from the claimed invention in that the coatings in the preferred embodiments are not disclosed as being shellac and/or polyvinylpyrrolidone and containing a further adjuvant. However, the use of these substances in coatings herein is disclosed. See, e.g., col. 10, lines 41-46 and Figures 2 and 3. The use of vinyl pyrrolidone is disclosed at col. 5, line 11. Suitable probiotic microorganisms are recited at col. 8, lines 13-30, including strains of *Lactobacillus* and *Bifidobacterium* (*Lactobacillus bifidus*).

In addition, Kim *et al.* and Sigurta disclose probiotic compositions suitable for administration for the same purpose as the tablet of Guttag wherein shellac and materials such as hydroxymethylcellulose and glycerin are used as coatings (See, e.g., Kim page 6, paragraph 2 and Sigurta, Examples.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the coated tablet of Guttag containing probiotic microorganisms according to the teachings of Guttag, Kim *et al.* and Sigurta regarding the use of a variety of coatings for the expected benefit of providing a composition that maintains viability, is palatable and is impervious to degradation by stomach acid in order to provide the protection and promotion of well-being that results from effective probiotic administration.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1651

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx
Primary Examiner
Art Unit 1651